determine if, on the basis of current scientific and medical knowledge, revision is warranted at this time. If so, the Committee will proceed to develop recommendations for revisions in a report to the Secretaries of HHS and USDA. The Committee shall be terminated upon delivery of its final report or at the end of two years, whichever is first.

The Departments invite nominations for committee membership of individuals qualified to carry out the above-mentioned tasks. Nominations should describe and document the nominee's qualifications in the relevant subject areas.

FOR FURTHER INFORMATION CONTACT: Elena T. Carbone, M.S., R.D., Co-executive Secretary from HHS to the Dietary Guidelines Advisory Committee, Office of Disease Prevention and Health Promotion, Public Health Service, U.S. Department of Health and Human Services, room 2132 Switzer Building, 330 C Street, SW., Washington, DC 20201, (202) 205–9007; or Debra Reed, M.S., L.N., Co-executive Secretary from USDA to the Dietary Guidelines Advisory Committee, Human Nutrition Information Service, U.S. Department of Agriculture, room 366, 6505 Belcrest Road, Hyattsville, Maryland 20782, (301) 436–8457.

ADDRESSES: Nominations may be submitted either to Elena T. Carbone or Debra Reed at the addresses above for up to 15 days after publication of this notice.

Philip R. Lee,

Assistant Secretary for Health, U.S. Department of Health and Human Services.

Ellen Haas,

Assistant Secretary for Food and Consumer Services, U.S. Department of Agriculture.

[FR Doc. 94–42 Filed 1–3–94; 8:45 am]

BILLING CODE 4160–17–M

Food and Drug Administration

[Docket No. 93E–0353]

Determination of Regulatory Review Period for Purposes of Patent Extension; Betaseron®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Betaseron® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biologic product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product Betaseron® (Interferon *beta*-1b). Betaseron® is indicated for use in ambulatory patients with relapsing-remitting multiple sclerosis to reduce the frequency of clinical exacerbations. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Betaseron® (U.S. Patent No. 4,588,585) from the Cetus Oncology Corp., and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated October 26, 1993, FDA advised the Patent and Trademark Office that this human biologic product had undergone a regulatory review period and that the approval of Betaseron® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Betaseron® is 3,720 days. Of this time, 3,319 days occurred during the testing phase of the regulatory review period, while 401 days occurred during the approval phase. These periods of time were derived from the following dates.

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* May 19, 1983. The applicant claims April 4, 1986, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 19, 1983, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 351 of the Public Health Service Act:* June 18, 1992. The applicant claims June 16, 1992, as the date the product license application (PLA) for Betaseron® (PLA 92–0495) was initially submitted. However, FDA records indicate that PLA 92–0495 was initially submitted on June 18, 1992.

3. *The date the application was approved:* July 23, 1993. FDA has verified the applicant's claim that PLA 92–0495 was approved on July 23, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,500 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 7, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA on or before July 5, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an

FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 17, 1993.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 94–36 Filed 1–3–94; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0416]

AVRE Inc.; Revocation of U.S. License No. 1074–003

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 1074–003) and the product license issued to AVRE Inc., (AVRE) for the manufacture of Source Plasma. AVRE has several locations. Only the Tacoma location is affected by this revocation. In a letter to FDA dated June 30, 1993, AVRE requested that its establishment and product licenses at the Tacoma location be revoked and thereby waived its opportunity for a hearing.

DATES: The revocation of the establishment license (U.S. License No. 1074–003) and the product license became effective November 8, 1993.

FOR FURTHER INFORMATION CONTACT: Jean M. Olson, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA announces the revocation of the establishment license (U.S. License No. 1074–003) and the product license issued to AVRE Inc., 10506 Bridgeport Way SW., Tacoma, WA 98499, for the manufacture of Source Plasma. Other locations under the AVRE license are not affected by this revocation. The licenses were revoked for the Tacoma location of AVRE only.

FDA inspected the Tacoma location of AVRE on April 7 through 21, 1993. During that inspection, FDA observed numerous deviations from the standards established in the license as well as the applicable Federal regulations. The inspection documented serious deviations from the applicable Federal regulations and standards established in the license. These deviations included, but were not limited to, the following:

1. Failure to follow adequate written standard operating procedures (SOP's) for determining donor suitability (21 CFR 606.100(b)), in that four donors were allowed to donate Source Plasma more than twice during a 7-day period; five donors were allowed to donate Source Plasma who had experienced a weight loss of greater than 10 pounds within a 2-month period without first being referred to a physician or physician substitute; and educational information provided to donors did not reference a temperature greater than 100.5 °F for more than 10 days as a symptom of acquired immune deficiency syndrome (AIDS).

2. Failure to follow adequate written SOP's for the collection, processing, storage, and distribution of blood and blood components for further manufacturing (21 CFR 606.100(b)), in that AVRE collected an amount of plasma from at least three donors that exceeded the maximum volume allowed by AVRE's plasma volume nomogram, AVRE's donor record files for at least 20 donors, 6 with multiple donations, did not contain photographs; and AVRE did not have its physician or physician substitute evaluate one donor who exhibited a temperature below 97.0 °F.

3. Failure to maintain complete, accurate, and concurrent records that clearly traced the steps of each significant procedure in the collection, processing, and storage of the blood products so as to provide a complete history of work performed (21 CFR 606.160), in that AVRE was unable to trace two unit numbers to the donors, AVRE misspelled the last name of at least one donor in the deferral file, and AVRE had no unit number in its donor record file for at least one donation.

4. Failure to observe, standardize, and calibrate equipment (21 CFR 606.60(a)), in that during October 1992, AVRE failed to clean the air filters on four Autopheresis-C machines.

FDA determined that the nature of the deficiencies found at AVRE showed a pattern of careless disregard for the standards established in the license and the Federal regulations that are designed to ensure the continued safety, purity, and potency of the manufactured product and that willfulness existed. The recent inspection showed that corrective actions promised in response to a March through April 1992 inspection, which resulted in suspension of AVRE's license, were not implemented or were not effective in achieving long-term compliance. In a letter to AVRE dated May 27, 1993, FDA delineated the observations listed above, provided notice that FDA intended to institute proceedings to revoke U.S. License 1074–003 issued to AVRE pursuant to 21 CFR 601.5(b). In accordance with 21 CFR 601.5(b), the letter advised AVRE that no additional time would be provided to achieve compliance with the regulations before FDA would institute proceedings to revoke the licenses of AVRE. The letter further announced its intent to offer an opportunity for a hearing. In a letter to FDA dated June 30, 1993, AVRE voluntarily requested that its licenses for the Tacoma location be revoked and thereby waived its opportunity for a hearing. In a letter dated November 8, 1993, FDA acknowledged voluntary revocation of the establishment license (U.S. License No. 1074–003) and the aforementioned product license of AVRE at the Tacoma location only.

FDA has placed copies of letters relevant to the license revocations on file under the docket number found in brackets in the heading of this document in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. These documents are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under 21 CFR 601.5 and section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 1074–003) and the product license issued to the Tacoma location of AVRE Inc., for the manufacture of Source Plasma were revoked, effective November 8, 1993.

This notice is issued and published under 21 CFR 601.8 and under authority delegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: December 16, 1993.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 94–37 Filed 1–3–94; 8:45 am]

BILLING CODE 4160–01–F